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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/702,228

11/05/2003

Michael R. Slater

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07/22/2008

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EXAMINER

VOGEL, NANCY TREPTOW

ART UNIT

PAPER NUMBER

1636

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/702,228 | <b>Applicant(s)</b><br>SLATER ET AL. |  |
|                              | <b>Examiner</b><br>NANCY VOGEL       | <b>Art Unit</b><br>1636              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) 13-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 68-74 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/19/08</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1-74 are pending in the case.

Receipt of the Information Disclosure Statement on 3/19/08 is acknowledged.

The reference which is struck through has not been considered since no copy was received.

The following is a new rejection necessitated by applicant's amendments to the claims:

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 and 68-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and by dependence claims 2-12 and 68-74 is vague and indefinite in the recitation of "is capable of being transcribed from the promoter", since the term "capable of" refers to a latent ability; it is unknown whether the ability is expressed or observed in the invention.

Claim 8 is vague and indefinite in the recitation of "the vector of claim which further comprises an open reading frame which includes the recognition site for the first restriction enzyme", since it is not clear how the recited open reading frame relates to the open reading frame(s) recited in claim 1.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5, 9, 68, 69, are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn et al. (US 6,248,569) in view of Thack (US Patent 5,342,782).

Dunn et al. teach a vector comprising a site for a first restriction site that generates a 3'TA overhang (i.e. PaeI) which is 5' to a site for a second restriction enzyme which generates blunt ends, (i.e. HpaI), and a promoter positioned 5' of the first site (See Fig. 2), such that DNA comprising an open reading frame inserted between the first and second site would have a 1 in three chance of being in frame with the open reading frame upstream of the first restriction site. (Dunn et al. also discloses a vector (Fig. 1A, 1B) comprising a first site for PaeI, with sites for blunt cutters such as ScaI and NruI 3' of said site, with a promoter positioned 5' to the first site). However, Thack teach that in order to obtain expression of an open reading frame of interest, it is placed in-frame downstream of a promoter in a vector teaches that one may adjust the sequence of an open reading frame such that it is in frame with a promoter upstream of the sequence, so that the correct reading frame is generated for the resultant protein

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(see col. 4, lines 36-65). It would have been obvious to one of ordinary skill in the art to have altered any out of frame sequence inserted in the vector of Dunn et al., in order to obtain the correct reading frame, as taught by Thack. The insertion of a sequence of interest into unique sites in a vector, using convenient sites, for expression of said sequence from a promoter on the vector, is a very well known method in the art, and such vectors are extremely well known and would have been obvious to one of ordinary skill in the art.

Claims 1-12 and 68-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn et al. in view of Thack as applied to claims 1-3, 5, 9, 68, 69, above, and further in view of Kappelman et al. (Gene, 160, 1995, 55-98) (cited by applicant) and New England Biolab catalog.

Kappelman et al. disclose the restriction enzyme Sgfl, which leaves 3'TA ends, and its 8 bp recognition site, and its usefulness for genome analysis (see abstract, see page 55). It would have been obvious to one of ordinary skill in the art to have inserted a well known site such as Sgfl in the vector of Dunn et al. in view of Thack, since the use of any particular restriction enzyme site in a vector is well known in the art, and since the placement of known and useful restriction sites, such as Sgfl, in any vector, for manipulation of DNA, was extremely well known in the art. The placement of Sgfl in a vector would result in well known sequences when joined to a DNA of interest, and when treated with restriction enzymes whose recognition sites, and cleavage sites, were well known in the art. In the absence of evidence to the contrary, the placement of any restriction site, in any vector or DNA sequence, was obvious to one of ordinary skill in

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the art. Restriction enzymes, their recognition sites, the nucleotides overhangs that they leave, and the sequences that are formed when DNA treated with said enzymes is joined with a particular DNA of interest, were well known, as was the manipulation of DNA using known and useful restriction enzymes, including inserting sequences encoding any restriction site, at any region of any DNA molecule. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY VOGEL whose telephone number is (571)272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/  
Primary Examiner, Art Unit 1636

NV  
7/18/08